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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/621,972

07/17/2003

Ross S. Tsugita

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10/24/2006

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EXAMINER

THALER, MICHAEL H

ART UNIT

PAPER NUMBER

3731

DATE MAILED: 10/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/621,972

Applicant(s)

TSUGITA, ROSS S.

Examiner

Michael Thaler

Art Unit

3731

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 32-52 is/are pending in the application.
- 4a) Of the above claim(s) 47-52 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 32-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>10/28/03, 6/3/05</u> | 6) <input type="checkbox"/> Other: _____ |

Claims 47-52 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on Oct. 10, 2006.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 32-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 32, line 6, there is no antecedent basis for "the catheter shaft".

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 32-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gray (WO 99/22673) in view of Patel (4,832,028). Gray discloses guidewire 30, filter 50 and stent

Art Unit: 3731

(page 6, lines 15-17). Gray fails to disclose a first shaft (claim 32) or outer catheter shaft (claim 41) with a balloon coupled thereto. However, Patel teaches that a guiding catheter 11 with a balloon 25 should be used with a dilating catheter 29 in order to obtain the advantage of guiding the dilating catheter 29 within the vasculature while the balloon 25 holds the guiding catheter in place (col. 1, lines 43-52 and col. 3, lines 15-27). It would have been obvious to use a guiding catheter with a balloon with the Gray dilating catheter so that it too would have this advantage. The guiding catheter is the claimed "first shaft" (claim 32) or "outer catheter shaft" (claim 41). As to claims 33 and 38, Gray fails to disclose that the stent is self expanding and is retained in a collapsed configuration by a retaining sleeve. However, it is old and well known in this art to make stents self-expanding in order to obtain the advantage of enabling them to automatically expand when released by the retaining sleeve. It would have been obvious to make the Gray stent self expanding so that it too would have this advantage. As to claim 40, note col. 2, lines 19-23 of Patel.

Claims 32-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garza et al. (4,665,918) in view of Hawkins et al. (4,790,812) and Patel (4,832,028). Garza et al. disclose

Art Unit: 3731

first shaft 78, guidewire 12, and stent 25. Garza et al. fail to disclose a filter coupled to the guidewire 12. However, Hawkins et al. teach that a filter 11 should be coupled to a guidewire 26 in order to obtain the advantage of capturing emboli or atheroma particles resulting from a procedure performed upstream in a blood vessel (col. 4, lines 25-29 and 47-51 and col. 5, lines 27-29. It would have been obvious to include a filter with the Garza et al. guidewire 12 so that it too would have this advantage during the Garza et al. stent deploying procedure which produces atheroma particles. Garza et al. fail to disclose a balloon coupled to the first shaft (the guiding catheter). However, Patel teaches that a balloon 25 should be coupled to a guiding catheter 11 in order to obtain the advantage of holding the guiding catheter in place (col. 1, lines 43-52 and col. 3, lines 15-27). It would have been obvious to include a balloon on the Garza et al. guiding catheter so that it too would have this advantage.

Claims 32-46 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 6,168,579. Although the conflicting claims are not identical, they are not patentably distinct from each other because the slight difference in the wording of the claims involves only an obvious difference.

Art Unit: 3731

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Thaler whose telephone number is (571) 272-4704. The examiner can normally be reached Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Application/Control Number: 10/621,972 .

Page 6

Art Unit: 3731

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A handwritten signature in black ink, appearing to read 'Michael Thaler', written in a cursive style.

MICHAEL THALER
PRIMARY EXAMINER
ART UNIT 3731